K101111

JUN 18 2010

XXV. Attachment 2: 510(k) Summary and Indications for Use statement

510(k) SUMMARY

BÂRRX Medical's HALO^{90} ULTRA Ablation Catheter Model 90-9200

1. Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared:

BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Phone: (408) 328-7302
Facsimile: (408) 328-7395

Contact Person: Viorica Filimon

Date Prepared: April 20, 2010

2. Name of device and Name/Address of Sponsor:

HALO^{90} ULTRA Ablation Catheter Model 90-9200

BÂRRX Medical Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

3. Common or Usual Name(s):

Electrosurgical Coagulation System

4. Classification Name:

Product code: GEI
CFR Section: 878.4400 Electrosurgical, cutting & coagulation & accessories
Device Class: II
Classification panel: General & Plastic Surgery

5. Predicate Devices

HALO^{90} Ablation Catheter model 90-9100 (K060169, K062723, K083737, and K093008) manufactured by BÂRRX Medical Inc.

6. Intended Use / Indications for Use

The HALO90 ULTRA Ablation Catheter model 90-9200 (when used with HALO^{FLEX} System) is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, Angiodysplasia, Gastric Antral Vascular Ectasia (GAVE) and Radiation Proctitis (RP).

7. Technological Characteristics

The HALO^{90} ULTRA Ablation Catheter model 90-9200 is a modification of the predicate device HALO^{90} Ablation Catheter model 90-9100 currently commercialized in USA. Both catheters have the same constructions, design, principle of operation, materials and energy density. The differences between HALO^{90} ULTRA and its predicate consist in the electrode surface increase and the associated components electrode cap and base.

HALO90 ULTRA Ablation Catheter model 90-9200 is used in conjunction with HALO^{FLEX} Energy Generator There are no changes associated to the HALO^{FLEX} Energy Generator software, hardware and accessories.

8. Substantial Equivalence

The HALO^{90} ULTRA Ablation Catheter model 90-9200 and the predicate devices HALO^{90} Ablation Catheter model 90-9100 are identical in construction except electrode and associated components (electrode cap and base) length change.

These differences were evaluated by performing the following Bench Tests and did not raise questions regarding safety and efficacy. Thus the devices are equivalent.

A- HALO90 ULTRA Ablation Catheter model 90-9200 Design Verification – Apposition

B- Tensile strengths of Base-cap & Litz wires

C- Attachment strength endoscope-elastomeric strap

D- Endoscope compatibility with the HALO^{90} ULTRA Ablation Catheter model 90-9200

E- Insertion- Retraction performance in a tissue model

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

Mr. Randall Sullivan
C.O.O.
BÂRRX Medical, Inc.
540 Oakmead Parkway
SUNNYVALE CA 94085

JUN 18 2010

Re: K101111
Trade/Device Name: HALO^{90} ULTRA Ablation Catheter Model 90-9200
Regulation Number: 21 CFR §878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: May 28, 2010
Received: June 1, 2010

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K101111

Device Name: HALO^{90} ULTRA Ablation Catheter model 90-9200

Indications for Use:

The HALO90 ULTRA Ablation Catheter model 90-9200 (when used with HALO^{FLEX} Energy Generator) is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to, the esophagus. Indications include Esophageal Ulcers, Mallory-Weiss tears, Arteriovenous Malformations, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, Angiodysplasia, Gastric Antral Vascular Ectasia (GAVE) and Radiation Proctitis (RP).

Prescription Use _X__ (Part 21 C.F.R. 801 Subpart D) AND/OR Over-The-Counter Use____ (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K101111